MEDICARE PART B
CHEMOTHERAPY ADMINISTRATION: PAYMENT AND POLICY
The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

**Office of Audit Services**

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

**Office of Evaluation and Inspections**

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

**Office of Investigations**

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

**Office of Counsel to the Inspector General**

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG’s internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.
EXECUTIVE SUMMARY

OBJECTIVE

To determine whether Medicare paid appropriately for Part B services billed as chemotherapy administration from 2005 to 2007.

BACKGROUND

Medicare Part B covers a limited number of outpatient prescription drugs and pays separately for their administration. Among the drugs covered by Part B are chemotherapy agents administered by injection or infusion in a physician’s office. Physicians who administer drugs to Medicare beneficiaries usually also purchase them and, therefore, bill Medicare Part B for both the drug and its administration. Sometimes, though, the drug the physician administers comes from another source, such as free samples given to the physician or a pharmaceutical company’s patient assistance program, and is not billed to Part B.

Medicare pays physicians about twice as much to administer chemotherapy drugs as it does to administer nonchemotherapy drugs. Medicare also pays the chemotherapy rate for administering certain types of nonchemotherapy drugs with particularly complex preparation and delivery issues. The Centers for Medicare & Medicaid Services (CMS) does not specify which particular nonchemotherapy drugs qualify for the chemotherapy rate (“qualifying drugs”), leaving that determination to the carriers with which CMS contracts to process Medicare Part B physician claims. Medicare paid $1.9 billion for chemotherapy administration services between 2005 and 2007.

We used two main data sources in this evaluation. First, we conducted structured interviews with and collected documents from appropriate carrier staff about their policies. We also analyzed Medicare Part B physician claims for services rendered and claimed between 2005 and 2007. To ensure a conservative estimate of inappropriate payments, we defined a qualifying drug for our Part B analysis as any drug that any carrier determined qualified for the chemotherapy administration rate.

We classified any chemotherapy administration claim that fell on a service date on which no qualifying drug was billed as an unmatched chemotherapy administration claim. We summarized unmatched chemotherapy administration claims data to the physician level to determine whether billing practices differed by specialty or claims volume.
EXECUTIVE SUMMARY

FINDINGS

Although unmatched claims exceeded $60 million from 2005 to 2007, Medicare data are insufficient to determine consistently whether chemotherapy administration payments are appropriate. We found that Medicare allowed $17.1 million for chemotherapy administration claims on days on which no drug was billed and $43.5 million for chemotherapy administration claims on days on which only nonqualifying drugs were billed. We cannot determine definitively whether these unmatched claims are truly inappropriate because we cannot eliminate the possibility that providers administered qualifying drugs but did not bill them to Medicare. Providers who submitted many chemotherapy administration claims overall tended to submit fewer unmatched claims as a percentage of their total.

Carriers have implemented inconsistent chemotherapy administration coding policies and review procedures. Lacking a national definition of “qualifying drug,” carriers have implemented their own policies and sometimes disagree on whether a particular drug qualifies for the higher administration rate. Two carriers have implemented claims processing edits to ensure that they pay the chemotherapy administration rate only for qualifying drugs; others say such edits would trigger inappropriate denials of legitimate claims. Six carriers have instead performed postpayment medical reviews that included chemotherapy administration claims.

RECOMMENDATIONS

Although the $60.6 million that we identified in unmatched chemotherapy administration claims is small compared to the $1.9 billion Medicare paid for Part B chemotherapy administration from 2005 to 2007, potential program savings may nevertheless exist if CMS can limit the use of chemotherapy administration codes to qualifying drugs. Furthermore, CMS’s policy of letting carriers determine which drugs qualify for billing with the chemotherapy administration codes has led to inconsistencies in how much carriers pay for the administration of certain drugs.

Therefore we recommend that CMS take the following actions:

- establish a process to determine which specific drugs qualify for the chemotherapy administration payment rate,
EXHIBIT 1: ANTIMYM IC THERAPY CLAIMS

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendation to instruct carriers to consider probe reviews of chemotherapy administration claims, but did not concur with the other three recommendations in our draft report.

CMS did not concur with our recommendation to clarify the criteria for qualifying drugs, stating that the current CPT guidance “represents the best consensus from the medical community and CMS.” CMS also stated that it believes the current variation in carrier definitions of qualifying drugs may be because of practice variations in the conditions for which a drug is used and that this variation may decrease as a consequence of contracting reform. We stand by our recommendation that CMS clarify its policy, but have revised the recommendation in a way that addresses practice variations.

CMS did not concur with our recommendation to use the current claims infrastructure to capture information about drugs not billed to Part B or our recommendation to develop edits to ensure that drug administration codes are billed correctly because it believes the implementation costs would exceed any benefit. Because our findings show that program savings may be achieved if CMS can ensure that chemotherapy administration codes are used appropriately, we stand by the intent of our original recommendations. However, we have amended them to defer to CMS’s judgment on the specific actions best suited to accomplish this goal.
# Table of Contents

**Executive Summary** ........................................... i

**Introduction** .................................................. 1

**Findings** ........................................................ 8

> Although unmatched claims exceeded $60 million from 2005 to 2007, Medicare data are insufficient to determine consistently whether chemotherapy administration payments are appropriate ................................................... 8

> Carriers have implemented inconsistent chemotherapy administration coding policies and review procedures ........... 9

**Recommendations** ............................................. 11

> Agency Comments and Office of Inspector General Response ... 12

**Appendixes** ..................................................... 14

> A: Methodology Notes and Limitations .......................... 14

> B: Complete List of Drugs With Conflicting Qualifying Determinations ................................................... 16

> C: Agency Comments ............................................. 17

**Acknowledgments** ............................................... 20
OBJECTIVE
To determine whether Medicare paid appropriately for Part B services billed as chemotherapy administration from 2005 to 2007.

BACKGROUND

Medicare Part B Drugs and Drug Administration Coverage
Medicare Part B covers a limited number of outpatient prescription drugs, including those that are furnished as an integral part of a physician’s service and are not usually self-administered. Examples of Part B drugs include the cancer chemotherapy drug doxorubicin (brand name Adriamycin), the anemia drug darbepoetin alfa (Aranesp), and the estrogen replacement estradiol valerate (Delestrogen). According to the Centers for Medicare & Medicaid Services’ (CMS) statistics, Medicare allowed about $2.4 billion for chemotherapy drugs and $7.4 billion for nonchemotherapy drugs in 2006.¹

In addition to covering certain drugs, Medicare Part B pays for the administration of covered drugs as a separate service. The American Medical Association’s (AMA) Current Procedural Terminology (CPT) contains the billing codes that physicians use to identify drug administration services when submitting claims to Medicare. Each drug administration CPT code identifies both the type of the drug delivered and the route of administration used. The CPT divides administration codes into three broad categories by drug type: (1) hydration; (2) therapeutic, prophylactic, and diagnostic injections and infusions; and (3) chemotherapy administration. Each drug type category lists several codes that describe different routes of administration, and some routes appear in multiple categories. For example, three codes describe the first hour of intravenous infusion—one for infusing a hydration solution, one for infusing a nonchemotherapy drug, and one for infusing a chemotherapy drug. Office of Inspector General (OIG) analysis of billing data shows that from 2005 to 2007, Medicare allowed about $1.9 billion for drug

administration codes from the chemotherapy category (“chemotherapy administration codes”) and $1.4 billion for drug administration codes from the other categories (“nonchemotherapy administration codes”).

Regardless of the route of administration, Medicare reimbursement is consistently higher for chemotherapy administration codes than for nonchemotherapy administration codes (see Table 1). For example, in 2008 Medicare allowed, on average, $161.49 for the first hour of intravenous chemotherapy infusion (plus payment for the drug itself). By contrast, Medicare would allow $73.89 for the same service if it involved a nonchemotherapy drug and $60.56 if it involved a hydration solution. According to the 2008 CPT Manual, “. . . chemotherapy services require advanced practice training and competency for staff . . . special considerations for preparation, dosage, or disposal; and . . . entail significant patient risk and frequent monitoring.”

<table>
<thead>
<tr>
<th>Route of Administration</th>
<th>Type of Drug Administered</th>
<th>Hydration Solution</th>
<th>Nonchemotherapy Drug</th>
<th>Chemotherapy Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial intravenous infusion, up to 1 hour</td>
<td></td>
<td>$60.56</td>
<td>$73.89</td>
<td>$161.49</td>
</tr>
<tr>
<td>Initial intravenous infusion, each additional hour</td>
<td></td>
<td>$18.28</td>
<td>$23.61</td>
<td>$36.18</td>
</tr>
<tr>
<td>Sequential intravenous infusion</td>
<td>-</td>
<td>-</td>
<td>$38.09</td>
<td>$79.60</td>
</tr>
<tr>
<td>Initial intravenous push</td>
<td>-</td>
<td>-</td>
<td>$57.89</td>
<td>$119.21</td>
</tr>
<tr>
<td>Sequential intravenous push</td>
<td>-</td>
<td>-</td>
<td>$25.52</td>
<td>$68.18</td>
</tr>
</tbody>
</table>


**Medicare Part B Drug Administration Billing**

Physicians submit claims for drugs and drug administration to entities called carriers with which CMS contracts to process Medicare Part B physician claims. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173 § 911, Social Security Act, § 1874A, 42 U.S.C. § 1395kk-1. Because carriers were the primary contractor type throughout our study period from 2005 to 2007, we will use the term “carrier” to refer to both types of Part B contractor throughout this report.

---


3 Starting in March 2007, CMS began shifting Part B claims processing responsibility to Part A/Part B Medicare Administrative Contractors as part of major contracting reform mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173 § 911, Social Security Act, § 1874A, 42 U.S.C. § 1395kk-1. Because carriers were the primary contractor type throughout our study period from 2005 to 2007, we will use the term “carrier” to refer to both types of Part B contractor throughout this report.
the physician submits to the carrier a standard paper or electronic claim form that contains information about the services performed. The carrier then passes the claim through a series of automated edits that verify that the claim is complete and meets Medicare coverage guidelines. Then the carrier calculates the correct reimbursement for the services claimed and issues payment to the physician. Most claims pass through this system rapidly, but edits sometimes trigger claim denials or flag claims for manual review by carrier staff.

Physicians who administer drugs to Medicare beneficiaries usually also purchase them and, therefore, bill Medicare Part B for both the drug and its administration. Several situations exist, however, in which Part B would receive a bill for the administration service but not the drug itself. For example, some Medicare Part D plans cover drugs also payable under Part B—if the beneficiary gets a drug through Part D, the plan submits data to the Part D contractor, not to the carrier. Alternatively, a pharmaceutical company may provide drugs at no cost as free samples, as part of a clinical trial, or under a patient assistance program. In this case, the physician would bill Part B for the administration service, but no claim for the drug would go to any segment of Medicare. Although the physician attaches a modifier to the administration claim to indicate that the service is part of a clinical trial, no such modifier exists to indicate if a drug comes from another source not billed to Medicare.4

Medicare Chemotherapy Administration Policy
Prior to January 1, 2005, Medicare allowed physicians to use the chemotherapy administration codes only to report the delivery of antineoplastic agents for cancer treatment.5 In December 2004, CMS issued Change Request (CR) 3631, which instructed carriers to allow the chemotherapy codes for “... parenteral administration of nonradionuclide anti-neoplastic drugs; and also to anti-neoplastic agents provided for treatment of noncancer diagnoses (e.g., cyclophosphamide for auto-immune conditions) or to substances such as monoclonal antibody agents, and other biologic response modifiers.” The new policy reflected changes to the CPT drug administration

4 Physicians who participate in CMS’s Competitive Acquisition Program (CAP) obtain drugs from CAP vendors, in which case the vendor submits the Part B drug claim to the carrier for payment. The physician also identifies the drugs on the administration claim but attaches a modifier that indicates that payment for them should go to the CAP vendor.

5 Antineoplastic drugs inhibit the growth of cancer cells.
categories that the AMA adopted in late 2004 but did not publish until the 2006 edition of the CPT manual. Hereinafter, we will refer to any drug that meets the CR 3631 criteria as a “qualifying drug.”

CMS did not identify specific qualifying drugs in CR 3631, stating, “[a]t this time, CMS is not developing a national list of approved chemotherapy drugs. CMS will allow each Medicare carrier to develop such a list.” As of September 2008, the “Medicare Claims Processing Manual” lists several examples of qualifying drugs but states, “[t]he drugs cited are not intended to be a complete list of drugs that may be administered using the chemotherapy administration codes. Local carriers may provide additional guidance as to which drugs may be considered to be chemotherapy drugs under Medicare.”6 CMS does not require, however, that carriers develop such guidance, nor does it require that carriers develop systems to ensure that chemotherapy administration codes are used only with qualifying drugs. According to the 2008 CPT Manual, chemotherapy administration codes should be reserved for drugs that “. . . [require] physician work and/or clinical staff monitoring well beyond that of therapeutic drug agents [i.e., those billed with the nonchemotherapy administration codes]. . . .”7

**Previous Work**

Previous analyses suggest that physicians sometimes misuse the chemotherapy administration codes. The Medicare Payment Advisory Commission (MedPAC) noted in a January 2006 report to Congress that many of the Medicare claims for chemotherapy administration that it reviewed did not have an accompanying drug claim. MedPAC also found that although Medicare payments for drug administration increased 217 percent from 2003 to 2004, payments for drugs increased only 10 percent.8

During preinspection for this study, we analyzed a 1-percent sample of CMS’s Part B Carrier 100 Percent National Claims History Line Item file for 2005. We found that Medicare allowed approximately $33 million that year for chemotherapy administration claims without a corresponding claim for a qualifying drug for the same day of service.

---

METHODOLOGY

We used two main data sources to develop the findings for this evaluation. To determine how Medicare carriers implemented CR 3631, we conducted structured interviews with appropriate staff from each carrier about its policies on the use of chemotherapy administration codes. We also collected and reviewed relevant documents from each carrier. We then applied the carrier policies to Medicare Part B claims data to determine whether providers used the codes appropriately.

Carrier Policy Analysis
We used publicly available CMS data sources to identify the 15 carriers that processed Medicare Part B claims between 2005 and 2007. We asked each carrier, by telephone and/or e-mail, about its implementation of CR 3631, its list (if any) of qualifying drugs, what guidance it had offered Medicare providers, and the results of any reviews of chemotherapy administration. We obtained documentation of these policies and reviews from the carriers and from CMS’s Medicare Coverage Database, an online compendium of contractor policies. Ten carriers that were in operation between 2005 and 2007 no longer hold Medicare contracts or have changed jurisdictions; in these cases, we obtained information about the prior carriers’ policies from the current contractor and from the Medicare Coverage Database.

We reviewed the carrier information to determine which drugs each carrier considered as qualifying.9 We then combined the carriers’ individual determinations to create an overall list of qualifying drugs for use in our claims analysis. To ensure a conservative estimate of inappropriate payments, we included a drug on this list if any carrier had determined that it qualified for the chemotherapy administration codes. We did not evaluate the appropriateness of the carriers’ determinations.

Medicare Claims Analysis
We systematically analyzed the Part B Carrier 100 Percent National Claims History Line Item files for services rendered and claimed between 2005 and 2007 to determine the incidence of chemotherapy administration coding errors. We first identified all drug claims and

---

9 One carrier had a policy that defined certain categories of drugs as qualifying or nonqualifying rather than identifying specific drugs by name. We used the national drug code listing and manufacturer and various medical resource Web sites to identify specific drugs in the categories defined by this carrier.
drug administration claims in the Part B files.\textsuperscript{10} We then counted the number of qualifying drug claims, nonqualifying drug claims, chemotherapy administration claims, and nonchemotherapy administration claims per beneficiary and service date. We then matched this summary service date information back to the drug and drug administration claims data. We classified any chemotherapy administration claim that fell on a service date on which no qualifying drug was billed as an unmatched chemotherapy administration claim.

To refine our analysis, we then sought to identify and eliminate unmatched claims that most likely appropriately described the administration of qualifying drugs that were not themselves billed to Part B. First, we eliminated claims that fell on service dates on which billed modifiers indicated that the beneficiary was enrolled in a clinical trial. We found 36,054 unmatched claims that occurred while the beneficiary was part of a clinical trial (see notes on clinical trials in Appendix A). Although Medicare data do not identify what drugs were provided to the beneficiary in the clinical trial, we assumed they were qualifying drugs and that the chemotherapy administration service was therefore billed appropriately. We then cross-referenced the remaining unmatched claims to Medicare Part D prescription drug event data to determine whether the claim could represent the administration of a Part D drug. Only one unmatched claim fell on a date on which the beneficiary had a supply of drugs paid for by Part D\textsuperscript{11} (see notes on the Part D match in Appendix A). We could not further refine our analysis because we found no data source that indicated whether beneficiaries obtained drugs from sources not billed to Medicare (see “Findings”). Nevertheless, we summarized unmatched chemotherapy administration claims data at the physician level to determine whether billing practices differed by specialty or claims volume.

\textsuperscript{10} We limited our analysis to drug administration codes describing injections and intravenous infusions because they appear in both the chemotherapy and nonchemotherapy CPT drug administration code categories. These services account for 99 percent of the chemotherapy administration services billed from 2005 to 2007.

\textsuperscript{11} We analyzed Part D prescription drug event data for January through June 2006. Because we found only one matching qualifying drug, we did not pursue the Part D analysis for other time periods.
INTRODUCTION

Standards
This study was conducted in accordance with the “Quality Standards for Inspections” issued by the President’s Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency (now Council of the Inspectors General on Integrity and Efficiency).
Although unmatched claims exceeded $60 million from 2005 to 2007, Medicare data are insufficient to determine consistently whether chemotherapy administration payments are appropriate. Based on our analysis, Medicare allowed $60.6 million for unmatched chemotherapy administration claims from 2005 to 2007. We classified any chemotherapy administration claim that fell on a service date on which no qualifying drug was billed as an unmatched chemotherapy administration claim. Approximately $700,000 of this amount derives from situations in which the provider billed a qualifying drug claim either the day before or day after the unmatched administration claim. Of the remainder, $17.1 million was allowed on days on which no drug was billed, and $43.5 million was allowed on days on which only nonqualifying drugs were billed. Table 2 shows the drugs that providers most commonly billed with unmatched administration claims of the latter category.

Table 2: Nonqualifying Drugs Frequently Appearing With Unmatched Chemotherapy Administration Claims

<table>
<thead>
<tr>
<th>Drug</th>
<th>Percentage of Unmatched Administration Claims</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydration Solutions</td>
<td>27 percent</td>
</tr>
<tr>
<td>Heparin Sodium</td>
<td>8 percent</td>
</tr>
<tr>
<td>Epoetin Alfa</td>
<td>8 percent</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>7 percent</td>
</tr>
<tr>
<td>Zoledronic Acid</td>
<td>7 percent</td>
</tr>
<tr>
<td>Darbepoetin Alfa</td>
<td>5 percent</td>
</tr>
</tbody>
</table>


Because claims data do not capture sufficient information, we cannot determine whether these unmatched claims are truly inappropriate. Specifically, Part B data do not identify drugs that are not billed to the program even when their administration is billed to Part B. Therefore, we cannot definitively conclude that unmatched chemotherapy administration claims do not represent the appropriately billed delivery.
of qualifying drugs themselves not billed to Part B. Without record review, which was not part of our methodology, we also cannot determine if an unmatched claim represents a billing error or omission. CMS and its carriers are bound by these same limitations.

Some carriers used the flexibility granted in CR 3631 to develop individual policies for chemotherapy administration coding. All 15 carriers implemented CMS’s policy expanding the application of the chemotherapy administration codes, and all communicated their policy to the provider community through bulletins, newsletters, provider meetings, and other vehicles or posted information on their Web sites. However, only four carriers developed comprehensive lists of all drugs and corresponding billing codes considered appropriate for use with the chemotherapy administration codes. Nine more created partial lists or classified particular drugs on a case-by-case basis, most often luteinizing hormone-releasing hormone analogs, which are used to treat prostate cancer. The remaining two have not specified any drugs that should be billed with particular administration codes. In one case, carrier officials elected not to create a list because they could not determine what drugs should be considered “biological response modifiers,” one category of qualifying drug identified in CR 3631.

Carriers have implemented inconsistent chemotherapy administration coding policies and review procedures

Carriers that made qualifying determinations sometimes disagreed on particular drugs. We identified 33 drugs that at least one carrier defined as qualifying and at least one other carrier defined as nonqualifying. Table 3 shows the six most commonly billed drugs that have conflicting definitions; the full list can be found in Appendix B.

Some carriers have implemented claims processing edits or conducted reviews to ensure correct billing of chemotherapy administration codes, but others have encountered difficulties or have focused on other priorities. Two carriers use claims processing edits that check for the presence of a qualifying drug claim before paying a chemotherapy administration claim. Several other carriers considered implementing
edits but ultimately did not because they believed that the edits would result in inappropriate denials when qualifying drugs were delivered but not billed to Medicare. Instead of edits, six carriers conducted postpayment medical reviews that included chemotherapy administration claims. Four of these carriers found instances in which providers used chemotherapy administration codes for nonqualifying drugs. Two other carriers have reviewed their administrative data and determined that chemotherapy administration coding does not appear to be problematic.
RECOMMENDATIONS

Compared to the overall $1.9 billion Medicare paid for Part B chemotherapy administration from 2005 to 2007, the $60.6 million in unmatched claims is relatively small. Nevertheless, potential program savings may exist if CMS can limit the use of chemotherapy administration codes to qualifying drugs. Furthermore, CMS’s policy of letting carriers determine which drugs qualify for billing with the chemotherapy administration codes has led to inconsistencies in how much carriers pay for the administration of certain drugs.

Therefore, we recommend that CMS take the following actions:

**Establish a Process to Determine Which Specific Drugs Qualify for the Chemotherapy Administration Payment Rate**

Some carriers have found the language in CR 3631 defining qualifying drugs to be overly broad, especially the term “biologic response modifiers.” As a result, carriers disagree on the drugs for which they allow the chemotherapy administration codes to be billed. While CMS believes that this variation may be an appropriate result of unique practices of large cancer centers, we note that no carrier defined qualifying drugs in terms of the clinical conditions or patient population for which the drug is used. Nevertheless, we recognize that a drug’s risk for adverse reaction may depend on such factors. Therefore, CMS should establish a process to determine if a given drug, under any reasonable circumstance, meets the CR 3631 definition of a qualifying drug. CMS should consult with the carriers and appropriate medical experts in developing this process. Once finalized, the process should be used to classify existing drugs as well as new drugs when they come to market. If a drug meets the qualifying criteria only under unique circumstances, CMS should instruct providers to bill, and carriers to allow, the chemotherapy administration rate only when those conditions are met.

**Instruct Carriers That Have Not Done So To Consider a Probe Review of Unmatched Chemotherapy Administration Claims**

The carriers that have reviewed chemotherapy administration coding have found numerous billing errors. CMS should instruct those carriers that have not conducted such a review to evaluate whether doing so would provide a favorable return on investment.
RECOMMENDATIONS

Ensure That Drug Administration Claims Are Coded Correctly and Paid Appropriately

Medicare Part B claims currently lack information needed to determine whether the correct administration code is used to bill for delivering a drug covered by Part B. However, our review suggests that ensuring that chemotherapy administration claims are appropriately coded could result in program savings. Therefore, we recommend that CMS take steps to ensure that drug administration claims are coded correctly and paid appropriately.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendation to instruct carriers to consider probe reviews of unmatched chemotherapy administration claims, but did not concur with the other three recommendations in our draft report. The full text of our original recommendations and CMS’s comments is provided in Appendix C.

In our draft report, we recommended that CMS clearly define the criteria for qualifying drugs. CMS did not concur with our recommendation, stating that the current CPT guidance “represents the best consensus from the medical community and CMS.” CMS also stated that it believes the current variation in carrier definitions of qualifying drugs may be because of regional practice variations in the conditions for which a drug is used and that this variation may decrease as a consequence of contracting reform. We stand by our recommendation that CMS clarify its policy, but have revised the recommendation in a way that addresses practice variations.

CMS concurred with our recommendation that carriers should consider probe reviews of chemotherapy administration claims if they have not already done so. CMS stated that it will instruct carriers that have not conducted probe reviews to evaluate whether doing so is appropriate. CMS further stated the Recovery Audit Contractors may be interested in this area.

In our draft report, we recommended that CMS ensure that the chemotherapy administration rate is paid only for appropriate drugs by using existing claims infrastructure to capture information about drugs not billed to Part B and instructing carriers to implement related system edits. CMS did not concur with these recommendations, stating that establishing a system to capture the required information would be
cost prohibitive and that edits were not appropriate because of provider practice variations. Nevertheless, our findings show that program savings may be achieved if CMS can ensure that chemotherapy administration codes are used appropriately. Therefore, we stand by the intent of our original recommendations, to ensure that drug administration claims are coded correctly and paid appropriately, but have replaced the two specific recommendations with a broader recommendation that defers to CMS's judgment on the specific actions best suited to accomplish this goal.
METHODOLOGY NOTES AND LIMITATIONS

Note on Clinical Trials
We considered a beneficiary to be in a clinical trial at the time of an unmatched chemotherapy administration claim as follows. We first identified all beneficiaries who had at least one drug or drug administration claim that carried a clinical trial billing modifier. For each such beneficiary, we then determined the earliest and latest service dates on which a clinical modifier appeared. Next, we defined the clinical trial date range as the span between the earliest and latest dates or, if that span was less than 60 days, between the earliest date and a date 60 days hence. If an unmatched chemotherapy administration claim fell into the clinical trial date range, we considered the beneficiary to be in a clinical trial on that date.

Note on Part D Match
Part D prescription drug event data include a start date for the prescription and the number of days’ supply covered by the claim. If the service date of an unmatched chemotherapy administration claim fell inside the window between the start date and the end of the supply, we considered the beneficiary on the claim to be receiving the Part D drug on the date of the unmatched claim. In total, 64 unmatched claims fell into a Part D window. Of the Part D drugs paid for at the time of these unmatched claims, 1 was an injectable antineoplastic, 1 was an injectable antiemetic, 2 were other injectable drugs, 1 was a topical anti-inflammatory, 7 were oral anticancer medications, and 52 were other oral medications.

Note on Limitations
Providers bill Medicare Part B separately for drugs and their administration and do not identify which administration line item pertains to which drug line item on a claim. Therefore, unless a provider bills on only one drug and one administration for a particular beneficiary and service date, no one can definitively determine which administration code is intended to go with which drug code. Because of this uncertainty and to ensure a conservative estimate, we defined unmatched chemotherapy administration claims as only those where no claim for a qualifying drug appeared for the same service date. In reality, there almost certainly exist additional unmatched chemotherapy administration claims on service dates where a provider billed only chemotherapy administration but also billed both qualifying and nonqualifying drugs on a particular date of service. Without
attempting to determine what portion is for unmatched chemotherapy administration claims, we note that Medicare Part B allowed $219 million for chemotherapy administration on service dates on which only chemotherapy administration codes, but both qualifying and nonqualifying drugs, were billed.
## Complete List of Drugs With Conflicting Qualifying Determinations

<table>
<thead>
<tr>
<th>Drug (Generic Name)</th>
<th>Qualifying Determinations (No. of carriers)</th>
<th>Nonqualifying Determinations (No. of carriers)</th>
<th>Number of Line Items (2005–2007)</th>
<th>Drug (Generic Name)</th>
<th>Qualifying Determinations (No. of carriers)</th>
<th>Nonqualifying Determinations (No. of carriers)</th>
<th>Number of Line Items (2005–2007)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abatacept</td>
<td>2</td>
<td>3</td>
<td>50,307</td>
<td>Filgrastim (300 mcg/ 480mcg)</td>
<td>2</td>
<td>4</td>
<td>1,474,819</td>
</tr>
<tr>
<td>Abciximab</td>
<td>2</td>
<td>3</td>
<td>1,303</td>
<td>Interferon Beta 1-a</td>
<td>3</td>
<td>1</td>
<td>187,173</td>
</tr>
<tr>
<td>Alefacept</td>
<td>2</td>
<td>3</td>
<td>14,640</td>
<td>Leucovorin Calcium</td>
<td>1</td>
<td>5</td>
<td>945,803</td>
</tr>
<tr>
<td>Antithymocyte Globulin, Rabbit</td>
<td>1</td>
<td>4</td>
<td>80</td>
<td>Leuprolide Acetate</td>
<td>4</td>
<td>4</td>
<td>3,902</td>
</tr>
<tr>
<td>Basiliximab</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>Mesna</td>
<td>5</td>
<td>1</td>
<td>27,453</td>
</tr>
<tr>
<td>Cyclosporine, parenteral</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>Natalizumab</td>
<td>5</td>
<td>1</td>
<td>14,610</td>
</tr>
<tr>
<td>Daclizumab</td>
<td>2</td>
<td>3</td>
<td>211</td>
<td>Octreotide</td>
<td>1</td>
<td>5</td>
<td>112,912</td>
</tr>
<tr>
<td>Decitabine</td>
<td>4</td>
<td>3</td>
<td>36,211</td>
<td>Omalizumab</td>
<td>3</td>
<td>3</td>
<td>77,066</td>
</tr>
<tr>
<td>Depo-Estradiol Cypionate</td>
<td>1</td>
<td>3</td>
<td>151,412</td>
<td>Oprelvekin</td>
<td>2</td>
<td>4</td>
<td>69,198</td>
</tr>
<tr>
<td>Digoxin Immune Fab (Ovine)</td>
<td>1</td>
<td>3</td>
<td>0</td>
<td>Palifermin</td>
<td>1</td>
<td>3</td>
<td>170</td>
</tr>
<tr>
<td>Eculizumab</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>Pegaptanib Sodium</td>
<td>1</td>
<td>3</td>
<td>112,102</td>
</tr>
<tr>
<td>Elliott’s B Solution</td>
<td>3</td>
<td>1</td>
<td>9</td>
<td>Pegfilgrastim</td>
<td>2</td>
<td>5</td>
<td>736,271</td>
</tr>
<tr>
<td>Estradiol Valerate (10 mg/20 mg)</td>
<td>2</td>
<td>2</td>
<td>39,193</td>
<td>Pentastarch 10 % Solution</td>
<td>1</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Estradiol Valerate (40 mg)</td>
<td>1</td>
<td>3</td>
<td>48,515</td>
<td>Sargramostim</td>
<td>1</td>
<td>5</td>
<td>278,325</td>
</tr>
<tr>
<td>Estrogen Conjugate</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>Tacrolimus</td>
<td>1</td>
<td>3</td>
<td>65</td>
</tr>
<tr>
<td>Estrone</td>
<td>2</td>
<td>2</td>
<td>6,119</td>
<td>Trimetrexate Glucoronate</td>
<td>1</td>
<td>3</td>
<td>457</td>
</tr>
<tr>
<td>Etanercept</td>
<td>1</td>
<td>4</td>
<td>35</td>
<td>Triptorelin Pamoate</td>
<td>7</td>
<td>1</td>
<td>189,159</td>
</tr>
</tbody>
</table>

TO: Daniel R. Levinson  
Inspector General

FROM: Charlene Frizzera  
Acting Administrator


Thank you for the opportunity to review and comment on the Office of Inspector General's (OIG) draft report entitled, "Medicare Part B Chemotherapy Administration: Payment and Policy." The OIG report addresses the appropriateness of Medicare payments for Part B services billed as chemotherapy administration from 2005 to 2007.

The Centers for Medicare & Medicaid Services (CMS) closely follows the Current Procedural Terminology (CPT) guidelines set forth by the American Medical Association (AMA) in determining whether the administration of a drug is billed using the chemotherapy codes or billed using the therapeutic, prophylactic, or diagnostic injection or infusion codes. Under CPT guidelines and as stated in the Internet Only Manual Claims Processing Manual, Chapter 12, Section 30.5, the chemotherapy administration codes apply to parenteral administration of non-radionuclide anti-neoplastic drugs; and also to anti-neoplastic agents provided for treatment of noncancer diagnoses (e.g., cyclophosphamide for auto-immune conditions) or to substances such as monoclonal antibody agents, and other biologic response modifiers.

The following drugs are commonly considered to fall under the category of monoclonal antibodies: infliximab, rituximab, alemtuzumab, gemtuzumab, and trastuzumab. Drugs commonly considered to fall under the category of hormonal anti-neoplastics include leuprolide acetate and goserelin acetate. The drugs cited are not intended to be a complete list but are intended as examples to be used as guidance for determining the types of drugs that should be administered using the chemotherapy administration codes.

OIG Recommendation

The CMS should clearly define the criteria for qualifying drugs. Specifically, the OIG states that a particular drug should not be considered qualified to be reported with chemotherapy administration CPT codes in one jurisdiction but not in another.
CMS Response

Although we appreciate the efforts of the OIG and the information it has collected and analyzed, we do not concur with this recommendation. The CPT guidelines that address this issue were developed by a special workgroup established by the AMA, which had CMS participation and input, and as requested by CMS pursuant to Section 303(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The workgroup’s recommendations were carefully reviewed and revised by the CPT Editorial Panel. At this time, CPT guidance represents the best consensus from the medical community and CMS regarding the appropriate CPT codes for reporting the administration of different types of drugs.

This variation noted by the OIG may result from certain characteristics of oncology practices that differ across jurisdictions. Large specialty cancer centers are unevenly distributed across the United States and the use of certain cancer drugs for certain clinical conditions or patient populations may be unique to these centers.

This variation may decrease as we reduce the number of Medicare contractors processing chemotherapy administration claims by moving to fully implement Medicare contracting reform, which will result in 15 Medicare Administrative Contractors (MACs) in operation. We will encourage Medicare contractor medical officers to continue to communicate with one another as they develop policies regarding drugs whose administration should be reported with chemotherapy administration CPT codes so that this variation may be minimized in the future as appropriate.

OIG Recommendation

The CMS should instruct carriers that have not done so to consider a probe review of unmatched chemotherapy administration claims.

CMS Response

We concur with the recommendation. CMS will instruct contractors that have not conducted probe reviews of unmatched chemotherapy administration claims that they should evaluate whether doing so is the most appropriate action consistent with their individual prioritized strategy. Recovery Audit Contractors may also be interested in conducting reviews in this area.

OIG Recommendation

The CMS should use existing claims infrastructure to capture information about drugs not billed to Part B.
CMS Response

We do not concur with this recommendation. A special system was developed to allow the submission of "no pay" claims for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals that cannot be used for other purposes without significant modification. At this time we believe the expense of developing a similar system for this purpose would outweigh any benefit.

OIG Recommendation

The CMS should direct Carriers to implement claims processing edits that verify that drug administration codes are appropriate for the drugs delivered.

CMS Response

We do not concur with this recommendation. As we stated above, we believe the CPT guidance represents the best consensus from the medical community and CMS regarding the appropriate CPT codes for reporting the administration of different types of drugs. For the reasons described elsewhere in this response letter, we do not believe it is appropriate at this time to develop edits to ensure that specific drugs are billed with specific drug administration codes.

We thank the OIG for your efforts regarding this study. We look forward to working with you as we proceed to address payment policies for chemotherapy administration, and are committed to ensuring high quality care for those Medicare beneficiaries affected by these policies.
ACKNOWLEDGMENTS

This report was prepared under the direction of Timothy S. Brady, Regional Inspector General for Evaluation and Inspections in the San Francisco regional office, and Deborah W. Harvey, Deputy Regional Inspector General.

Scott Hutchison served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the San Francisco regional office who contributed to the report include Veronica Gonzalez, Christina Lester, and China Tantameng; central office staff who contributed include Kevin Manley.